

-8-

**REMARKS**

This amendment is responsive to the Office Action of September 20, 2005. Reconsideration and allowance of claims 1-11, 17, 18, 20-22, and 24-28 are requested.

**The Office Action**

Claims 1-7 and 28 stand rejected under 35 U.S.C. § 103 as being obvious over Fuller (US 5,792,668).

Claim 8 stands rejected under 35 U.S.C. § 103 as being obvious over Fuller in view of Nappholz (US 5,113,869).

Claim 9 stands rejected under 35 U.S.C. § 103 as being unpatentable over Fuller, in view of New (US 6,494,829).

Claims 10 and 21 stand rejected under 35 U.S.C. § 103 as being unpatentable over Fuller, in view of Papadakis (US 5,461,921).

Claim 11 stands rejected under 35 U.S.C. § 103 as being unpatentable over Fuller in view of Papadakis, further in view of Feldman (US 5,265,613).

Claims 17, 18, 20, 24, 25, 26, and 27 stand rejected under 35 U.S.C. § 103 as being obvious over Fuller in view of Abraham (US 6,407,978).

Claim 22 stands rejected under 35 U.S.C. § 103 as being unpatentable over Fuller in view of Kinast (US 5,995,858).

**The Present Application**

Each type of modern electronic equipment has one or more characteristic oscillation frequencies. In the medical field, for example, defibrillators often transmit high frequency signals into the body to determine the impedance of the defibrillator electrodes. In ultrasonic imaging, ultrasound signals are transmitted and echoes received to image tissue or blood flow. Pulse oximeters transmit pulses of red or infrared light energy into the body and measure transmitted infrared light to determinate oxygen saturation levels and pulse rate. Other devices simply detect electrical signals, e.g., an electrocardiogram. Many other types of electronic equipment are also used to make measurements of a physiological state of a patient,

-9-

each having one or more characteristic operating frequencies. Moreover, other electronic equipment such as power lines, fluorescent lights, mobile phones, television transmissions, radio transmissions, oscillators in various medical and non-medical electronic equipment, and the like, typically permeate medical diagnostic areas.

When medical diagnostic measurements are taken using frequencies which overlap or are harmonics of other signals already present in the room, interference can occur which can result in erroneous, misleading or noisy readings.

If one knows in advance exactly which frequencies will be present in a medical facility, one can design equipment, such as the equipment discussed above, to operate at different, non-interfering frequencies. However, the frequencies at which contaminating signals are present vary from region to region and even from room to room within a medical facility. The contaminating frequencies present in a medical examination area are dependent upon not just the nature of the other types of electronic equipment in the room, but also their manufacturer. Accordingly, it is extremely difficult, if even possible, to predict in advance which measurement frequencies will be free from contaminating frequency signals.

If one were to make such a determination for one area in which patient diagnostic information is to be measured, the determination could be invalid for other areas in which other equipment, etc., is present. Hence, one could overcome the interference problem by designing custom measurement devices for each measurement area in each facility. However, designing measurement devices which are so location dependent is commercially impractical. Moreover, even if the measurement device operated at a measurement frequency which is free from contamination frequencies when designed and introduced into the measurement area, other equipment which is brought in later could interfere.

The present application addresses the problem of how to design a medical measurement device which is free from measurement errors due to noise signals at contaminating frequencies in the room when the frequencies of such contaminating noise signals are unknown in advance.

-10-

**The References of Record**

The references cited and applied by the Examiner do not address the above-discussed noise problem nor do the references of record provide a solution to this problem.

The Fuller reference is directed to radiofrequency spectroscopy (column 1, lines 15-16). In spectroscopy, a substance is irradiated at a plurality of energies, i.e., frequencies, and the curve or function of frequency versus response is evaluated. More specifically, reflected and/or transmitted signal real and imaginary components at the specimen are spectrally examined as a function of frequency to identify the presence and/or concentration of the chemical of interest (column 2, lines 47-50).

More specifically, chemical substances have natural resonant frequencies which are a function of the chemical bonds in the chemical. When the chemical is irradiated with a spectrum of different frequencies, it absorbs signal components at the resonant frequencies more strongly and signal components at other frequencies more weakly. Analogously, when the broad spectrum excitation signal is stopped, the chemical will emit signals at its resonance frequencies. Chemicals which have different bonds, have a different pattern of resonance versus non-resonance frequencies. This frequency versus amplitude of response can be considered the signature of the chemical. Exemplary signals are illustrated in Figure 4C of Fuller.

Fuller looks not only at the characteristic signatures to identify the chemical present, but also looks at the phase shift between the transmitted and reflected signals to obtain greater specificity regarding the presence and/or concentration of analytes or chemicals of interest (column 2, lines 51-56).

Thus, the technique of Fuller requires irradiation of the target substance with a spectrum of frequencies in order to perform in its operative and intended manner. Because Fuller has an *a priori* knowledge that there will be a limited number of analytes and chemicals in the sample, it may not be necessary to irradiate the sample at every frequency of the spectrum. However, in order to distinguish among the potential analytes and chemicals, Fuller needs to irradiate the sample at a sufficient number of the frequencies which are known to be resonant frequencies of some of the analytes or chemicals but not others in order to gather a sufficient set of

-11-

data to perform his analysis. Thus, Fuller needs to irradiate the target with a plurality of known frequencies, not just any frequency chosen at random.

Fuller does not irradiate the sample with multiple frequencies for purposes of avoiding interference or for determining whether some of the measurements are contaminated by stray radio frequency signals from other devices. Rather, Fuller irradiates the sample with a plurality of frequencies because such multi-frequency irradiation is a necessary element of his spectroscopic measurement technique.

**Abraham** is not analogous prior art to either the present application or to Fuller. Abraham is directed to multiplexing data and information carried over power lines. Abraham tells the reader nothing about spectroscopic analysis, taking medical measurements in areas where there are stray signal components which can interfere with the medical measurements, or the like.

**The Claims Distinguish Patentably  
Over the Prior Art of Record**

**Claim 1** calls for generating randomly selected frequencies which are randomly changed. The Examiner concedes the Fuller does not generate frequencies at random, but asserts that "the frequencies could have been generated at random". First, the applicants inquire which part of 35 U.S.C. makes that which was not disclosed by a reference but "could have been" a category of prior art.

Moreover, Fuller could not use random frequencies. Fuller could not use just any frequency. Rather, than randomly selected frequencies, Fuller needs frequencies from which the spectral signature associated with a target chemical can be recognized (column 10, lines 20-21). Similarly, when measuring phase shift for concentration, frequencies with substantial insensitivity to other chemicals which are typically present are selected (column 17, lines 60-61; Figure 7C). If such regions of insensitivity cannot be identified, then a sufficient number of frequencies with a known relative sensitivity to potentially present analytes or chemicals must be used so that the concentration image can be deconvolved from the set of measurements. Thus, it is submitted that Fuller teaches against randomly selecting frequencies in favor of selecting specific frequencies. When there is noise on one or more of

-12-

Fuller's characteristic frequencies, Fuller is susceptible to result degradation or error due to the noise.

Because Fuller provides no motivation to randomly select frequencies and randomly change them, it is submitted that **claim 1 and claims 3, 10, and 11 dependent therefrom** distinguish patentably and unobviously over the references of record.

Dependent **claim 10** further calls for making ultrasound measurements at the randomly changed frequencies. Although Papadakis does show that ultrasound is known for flaw detection, there is no suggestion or motivation in either Papadakis or Fuller to perform the ultrasonic examination at randomly changed frequencies. Rather, as Papadakis explains at column 1, line 66 – column 2, line 11, the energy (frequency) of the ultrasound signal determines the nature or size of the detected flaws. Random frequency selection would randomly miss some flaws. Thus, Papadakis wants a wide-band continuous wave (column 3, lines 6-9). Accordingly, it is submitted that **claim 10 and claim 11 dependent therefrom** distinguish patentably and unobviously over the references of record.

**Claim 17** is directed to a device for measuring a desired physiological condition of a patient while avoiding degradation inaccuracy of the measured physiological conditions due to interference from nearby electronic equipment. Fuller does not address the issue of interference from nearby electronic equipment for curing this problem. Abraham does not cure this shortcoming of Fuller. Rather, Abraham addresses how to multiplex multiple signals on power lines. Abraham provides no motivation or teaching to one in possession of the Fuller invention which would motivate such person to address the issue of interference from nearby electronic equipment. Because neither Fuller nor Abraham address, much less teach or motivate one regarding the avoidance of interference from nearby electronic equipment, it is submitted that they do not render claim 17 obvious.

Moreover, claim 17 calls for a random number generator and a divider which receives a clock signal and generated random numbers to generate a randomized clock signal which is used by a transmitting means and a detecting means to transmit and detect signals at random frequencies. Fuller makes no suggestion of using random frequencies for the described spectroscopic analysis. Abraham

-13-

provides no motivation to alter a spectroscopic analysis system. Indeed, Abraham addresses multiplexing signals on power lines. At best, Abraham goes to enablement by showing that random number generators are known; but, Abraham provides no motivation to those working in the spectroscopy arts to alter spectroscopy processes. Accordingly, it is submitted that **claim 17 and claims 25 and 26 dependent therefrom** distinguish patentably and unobviously over the references of record.

**Claim 25** calls for an analyzing means which determines the impedance at each of the transmitted and detected frequencies and **claim 26** adds that the analyzing means analyzes the measured physiological condition at each frequency for consistency. Inconsistent measurements are indicative of interference. Fuller makes no suggestion of measurement physiological conditions at each of a plurality of frequencies for consistency, nor does Fuller suggest that inconsistent measurements are indicative of interference. To the contrary, the spectroscopic analysis performed by Fuller requires data obtained at different frequencies. There is not suggestion in Fuller that some of this data should be discarded or that inconsistencies might be an indication of interference. Abraham does not address or cure this shortcoming. Accordingly, it is submitted that **claims 25 and 26** distinguish patentably and unobviously over the references of record.

**Claim 18** is directed to a spread spectrum measurement device which measures a physiological condition such as heart rate, blood flow, blood pressure, respiration rate, contact impedance, image tissue, make blood oximetry measurements, or the like. Fuller performs a chemical analysis to analyze chemicals which are present in a biological sample. No suggestion or enabling disclosure is provided for making such physiological measurements with the Fuller device. The Abraham patent which addresses multiplexing data signals on power lines describes no technique for modifying or revising the Fuller device such that it could make such measurements. Accordingly, it is submitted that **claim 18** distinguishes patentably and unobviously over the references of record.

**Claim 20** calls for a random signal generator configured to generate a clock signal that is used to change a frequency of the electrical input signal directed to the medium randomly around a selected frequency spectrum by randomizing the clock signal with a random number generator and a divider. Fuller does not apply

-14-

random frequencies, nor does Fuller randomly change frequencies. Indeed, Fuller has neither a randomizer for performing such functions nor provides any motivation for adding such function to the disclosed spectroscopy device. Abraham discloses a random number generator, but for a non-analogous, different purpose – carrying communications over power lines. Abraham provides no motivation to modify the Fuller spectroscopic device to change frequencies of the input signal randomly around a selected spectrum. Accordingly, it is submitted that **claim 20 and claim 27 dependent therefrom** distinguish patentably and unobviously over the references of record.

Dependent **claim 27** calls for determining at least one of contact impedance, heart rate, and respiration rate from the analyzed spread spectrum signal. Neither Fuller nor Abraham provide any enabling disclosure as to how to measure contact impedance, heart rate, or respiration rate from the output signal of the Fuller spectroscopic device. Accordingly, it is submitted that **claim 27** distinguishes patentably and unobviously over the references of record.

**Claim 28** calls for analyzing the detected signals to generate a plurality of seemingly redundant measurements, at least one of which is isolated from interference. Fuller, being a spectroscopic technique, uses data at a plurality of frequencies to generate a single measurement. Fuller makes no suggestion of making redundant measurements at different frequencies. Moreover, Fuller does not address the issue of interference, much less provide any motivation how to address and cure any interference problems. Accordingly, it is submitted that **claim 28 and claims 21 and 22 dependent therefrom** distinguish patentably and unobviously over the references of record.

**Claim 21** calls for the transmitter to transmit an ultrasound signal. Papadakis discloses an ultrasound flaw detector. In Fuller, the resonant frequencies which are addressed are in the radio frequency range. If one were to substitute an ultrasound transmitter for the radio frequency transmitter of Fuller, it would no longer excite discussed resonance energies of the materials and be inoperative for its intended purpose. Nothing in Papadakis shows how to cure this defect. Accordingly, it is submitted that **claim 21** distinguishes patentably and unobviously over the references of record.

-15-

**Claim 22** calls for the transmission of the spread spectrum light signal. Again, neither Fuller nor Kinast provide any enabling disclosure regarding how the Fuller spectroscopic device could be changed from radio frequency to light frequency and still achieve its intended purpose. Accordingly, it is submitted that **claim 22** distinguishes patentably and unobviously over the references of record.

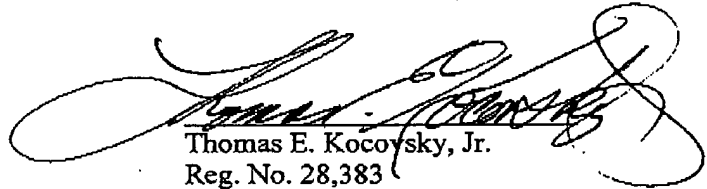
### CONCLUSION

For the reasons set forth above, it is submitted that claims 1-11, 17, 18, 20-22, and 24-28 distinguish patentably and unobviously over the references of record. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is requested to telephone Thomas Kocovsky at (216) 861-5582.

Respectfully submitted,

FAY, SHARPE, FAGAN,  
MINNICH & McKEE, LLP



Thomas E. Kocovsky, Jr.  
Reg. No. 28,383  
1100 Superior Avenue  
Seventh Floor  
Cleveland, OH 44114-2518  
(216) 861-5582

L:\HMM\DATA\2005\PKRZ201003.AMN.DOC